

ED

**Notice of Allowability**

Application No.

10/756,945

Examiner

Benjamin Huh

Applicant(s)

LANDAU ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/28/07.
2. ☒ The allowed claim(s) is/are 1-20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

KEVIN C. SIRMONS  
 SUPERVISORY PATENT EXAMINER



## ALLOWANCE

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Peter Heuser on 3/23/07 & 3/28/07.

The application has been amended as follows:

#### IN THE CLAIMS:

Claim 1 line 6 after "the marking assembly being fluidly coupled" delete "with" and insert --within--

Claim 1 line 7 after "assembly is activated" delete "upon" and insert -- by --

Claim 8 line 6 after "selectively apply" insert --the--

Claim 8 line 8 after "fluidly coupled with the" delete "needle-free injection device" and insert -- pressurized gas delivery mechanism --

Claim 8 line 9 after "exhaust gas from the" insert --pressurized --

Claim 13 line 10 after "gas delivery mechanism to" insert -- activate --

Claim 14 line 8 after "assembly is activated" delete "upon" and insert --by--

The following is an examiner's statement of reasons for allowance: Claims 1-11 & 14-20 are allowed because the recited combination of elements of a needle-free injection device comprising a syringe assembly for drawing in and expelling fluid upon application of pressurized gas from a pressurized gas delivery mechanism or gas reservoir and a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred, the marking assembly being fluidly coupled within the needle-free injection device, such that the marking assembly is activated by the post-injection venting of the pressurized gas or the post-injection exhaust gas from the pressurized gas delivery mechanism of the needle-free injection device upon the conclusion of an injection sequence is not found nor fairly taught in the prior art of record, as argued by applicant and agreed by examiner. The examiner would like to note that it is the examiner's position that the marking assembly is activated explicitly by the vented gas or exhaust gas which occurs upon the conclusion of the full injection sequence which means the drug/therapeutic has been administered/delivered.

Claims 13 is allowed because the recited combination of elements of a needle-free injection device comprising a syringe assembly configured to expel injectable fluid out of a nozzle upon application of pressurized from the gas reservoir to the syringe assembly; a gas reservoir; a pressurized gas delivery mechanism adapted to apply pressurized gas to the syringe assembly; a marking assembly configured to place a mark on or near an injection site to indicate an injection has occurred; and an exhaust

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gas pathway configured to direct at least a portion of the post-injection exhaust gas from the pressurized gas delivery mechanism to activate the marking assembly upon the conclusion of a full injection sequence is not found nor fairly taught in the prior art of record, as argued by applicant and agreed by examiner.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

Handwritten signature of Kevin C. Sirmons in cursive script.